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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,909	12/18/2001	Heather L. Davis	C1039/7058(HCL X04/19/02)	8458

7590 03/26/2003

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EXAMINER

LI, BAO Q

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,909	DAVIS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 8-33, drawn to a method of inducing an antigen specific immune response comprising administering to the subject a CpG dinucleotide and a non-nucleic acid adjuvant that producing a depo effect, classified in class 435, subclass 5.
- II. Claims 1, 4, and 8-33, drawn to a method of inducing an antigen specific immune response comprising administering to the subject a CpG dinucleotide and a non-nucleic acid adjuvant that producing an immune stimulating effect, classified in class 435, subclass 6.
- III. Claims 1, 6-7, 8-33, drawn to a method for inducing an antigen specific immune response comprising administering to the subject a CpG dinucleotide and a non-nucleic acid adjuvant that producing both an immune stimulating and a depo effects, classified in class 424, subclass 278.1.

Please note if any or above group is elected, Applicants are further requested to select one kind of antigen selected from Group consisting of (1) a virus antigen, (2) a bacterial antigen, (3) a parasite antigen, (4). a tumor antigen, (5) an allergen for the examination on the merits. because different antigens have different structures and functions, they works in different modes and produce different immune responses. They exhibit different patentable weights. The combination utilization of any adjuvants with a CpG motif will change an immune response that constitute distinct inventions.

Please note if any or above group is elected, Applicants are further requested to select one kind of an X1X and X3X4 CpG sequence listed in claims 20-23 to be examined on the merits because different sequences of CpG motifs have different patentable weights and constitute distinctive inventions.

Please note if any one of groups I or III is elected, Applicants are further requested to select one kind of a depo effect adjuvant selected from the group consisting of (1) alum, (2). emulsion-based formulations, (3). mineral oil, (4). non-

mineral oil, (5). water-in-oil emulsion, (6). oil-in-water emulsion, (7). Seppic ISA series, (8) MF-59 and (9). PROVAX. Because different adjuvants have different structures and functions. They work in different modes and have different patentable weights. The combination utilization of any adjuvants with a CpG motif will change an immune response that constitute distinct inventions.

Please note if any or above group is elected, Applicants are further requested to select one kind of immune stimulating adjuvants selected from group consisting of (a) PCPP polymer, (b) derivative of polysaccharides, (c) MPL, (d). MDP, (e) t-MDP, (f) OM-174 and (g) Leishmania elongation factor. Because different adjuvants have different structures and functions. They works in different modes for producing adjuvants effects and constitutes different patentable weights. The combination utilization of any adjuvants with a CpG motif will change an immune response that constitute distinct inventions.

Please note if any or above group is elected, Applicants are further requested to select one kind of adjuvants that have a depo effect and stimulating effect. They are selected from the group consisting of (i) ISCOMS, (ii) SB-AS2, (iii) SB-AS4, (iv) non-ionic block copolymers, and (v) SAF. Because different adjuvants have different structures and functions. They works in different modes for producing adjuvants effects and constitutes different patentable weights. The combination utilization of any adjuvants with a CpG motif will change an immune response that constitute distinct inventions.

- IV. Claims 1, 34, drawn to method of inducing an antigen specific immune response by combination of CpG and another adjuvant, whereas the immune response is an immune response switched from Th 2 to Th1 response, classified in class 514, subclass 44.
- V. Claims 1, 35, drawn to method of inducing an antigen specific immune response by combination of CpG and another adjuvant, whereas the immune response is an immune response switched from Th1 to Th2 response, , classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1648

Inventions of Groups I-V are mutually exclusive and patentably distinct methods each are structurally and functionally different. The multiple methods have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes, in house and commercial databases, and scientific literature and would require the consideration of different patentability issues.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

March 24, 2003


JAMES HOUSEL 3/24/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600